

Remarks:

Claims 1-28 are pending in the application. In the Office action dated July 6, 2007, claim 27 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 8-13 and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by Poole (US 6,158,431). Claims 15 and 21-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Poole. Claims 6, 7 and 16-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Poole, as applied to claims 1 and 15 above, and in view of Poole et al. (US 5,278,626). Claims 1-5, 8-14 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. (US 6,234,167) in view of Poole.

Responsive to the Office action, claims 1, 2, 15, 27, and 28 are amended. In view of the amendments above, and the remarks below, Applicants respectfully request reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 U.S.C. § 112

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention.

Specifically, the Examiner suggests that claim 27 is redundant on itself, and that it is not clear what is involved with configuring the controller because there appears to be a typographical error.

Page 9 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3

Applicants have amended claim 27 to clarify the claimed subject matter. Applicants take this opportunity to amend the specification at page 13, line 10, in order to clarify the existing support for the amendment to claim 27.

In view of the above amendments, Applicants respectfully request the withdrawal of the rejection to claim 27 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 USC § 102

Claims 1, 8-13 and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by Poole (U.S. Patent no. 6,158,431).

Specifically, the Examiner asserts that Poole discloses an inhaler that incorporates the elements of the medicament dispensers of claim 1 and of claim 28. Without acknowledging the propriety of the rejections, Applicants have amended claims 1 and 28 in order to more particularly define their invention.

Specifically, Applicants have amended claim 1 to recite a medicament dispenser that includes an accumulator in fluid communication with the ejector and a valve intermediate the medicament supply and the accumulator. Applicants have amended claim 28 to place it into more conventional form, and to recite an inhaler that includes an accumulator means, and a means for regulating an addition of medicament to the accumulator means from the fluid medicament supply means.

As shown by Poole in Fig. 3, reproduced below, and discussed at col. 7, lines 26-37, the fluid feed assembly 14 of Poole includes a vial 80 that contains a therapeutic solution. Advancement of piston 82 drives the fluid through a hollow needle 86 and through flexible tube 88 to droplet generator 16.

Page 10 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3

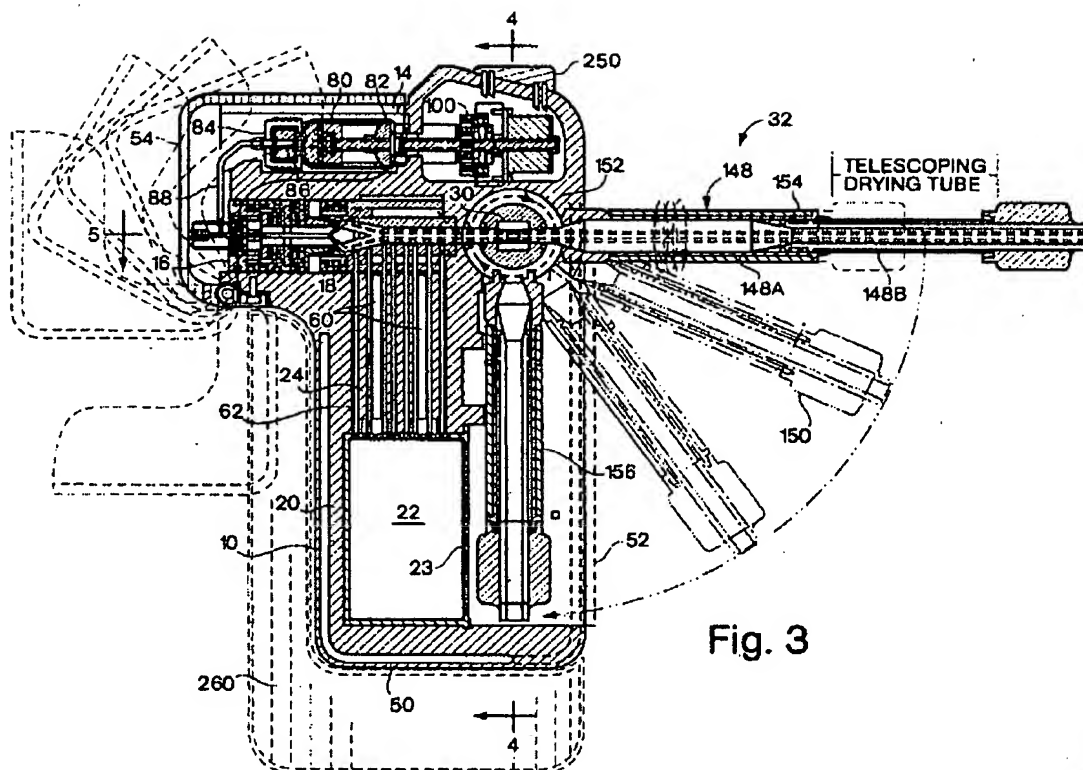


Fig. 3

Poole therefore fails to disclose a device having an accumulator that is distinct from the therapeutic fluid supply, and fails to disclose any valve or regulator between the fluid supply and the ejector. Any movement of the piston 82 results in a change in the fluid delivered to the droplet generator, specifically in that retrograde motion of the piston can be used to draw fluid away from the orifices in the droplet generator (see page 7, lines 48-51).

As the inhaler of the Poole reference fails to disclose an accumulator in fluid communication with the ejector, and a valve intermediate the medicament supply and

the accumulator, Applicants suggest that the Poole reference fails to anticipate the dispenser of claim 1. As claims 8-13 depend directly or indirectly from claim 1, Applicants suggest they are similarly not anticipated by Poole.

Applicants further suggest that the Poole reference fails to describe an inhaler having a means for accumulating fluid medicament that it is in fluid communication with an ejector means, and a means for regulating an addition of medicament to the accumulator means from the fluid medicament supply means. Applicants therefore suggest that the Poole reference similarly fails to anticipate the inhaler of claim 28.

In view of the amendments and remarks above, Applicants respectfully request the withdrawal of the rejection of claims 1, 8-13, and 28 under 35 U.S.C. § 102.

Rejections under 35 USC § 103

Claims 15 and 21-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Poole (U.S. Patent no. 6,158,431).

The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing Poole's device, to perform the recited steps of claim 15 in order to calibrate the inhaler. Applicants disagree.

However, in the interest of facilitating the prosecution of the application, Applicants have amended claim 15 to specify that the medicament inhaler of the claimed method includes a medicament accumulator in fluid communication with the medicament supply, and a valve intermediate the medicament supply and the medicament accumulator.

Page 12 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3

As discussed above, the delivery system of Poole does not include an accumulator, nor does it include a valve intermediate the medicament supply and the medicament accumulator. The Poole reference therefore fails to establish the *prima facie* obviousness of claims 15, and 21-27 for failing to disclose each and every element of the rejected claims.

Furthermore, the Poole reference fails to provide a suggestion or motivation to modify the delivery system in order to arrive at the claimed inhaler. As discussed above, by having a single fluid pathway from the fluid feed assembly to the droplet generator, the orifices of the droplet generator of Poole can be kept clean by reversing piston driver 100, thereby withdrawing the medicament fluid from the droplet generator 16. The presence of a valve or an accumulator between the vial 80 and droplet generator 16 would interfere with this advantageous property of the Poole device.

Where a modification to the prior art would change the principle of operation of the cited reference, or render it unsatisfactory for its intended purposes, there can be no motivation or suggestion to modify the reference as suggested by the examiner.

For at least these reasons, Applicants suggest that the Examiner has failed to establish the *prima facie* obviousness of claims 15 and 21-27, and they respectfully request the withdrawal of the rejection of the claims under 35 U.S.C. § 103.

Page 13 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3

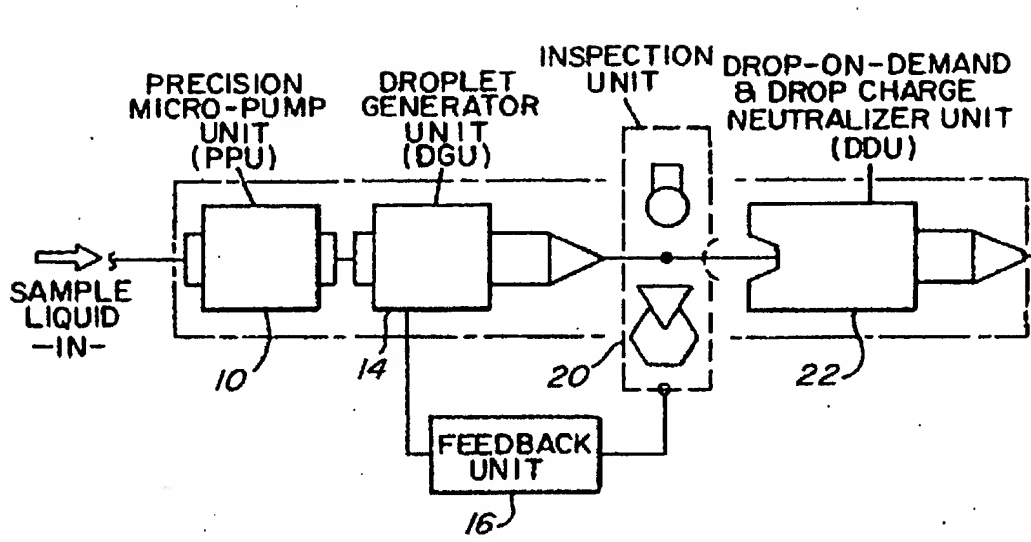
Claims 6, 7 and 16-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Poole (U.S. Patent no. 6,158,431), as applied to claims 1 and 15 above, and further in view of Poole et al. (US 5,278,626).

The Examiner suggests it would have been obvious to one of ordinary skill in the art at the time of the invention to use drop volume or weight for the performance characteristic instead of drop size for a more accurate determination of the amount of medication being delivered to the patient with each drop. Applicants respectfully disagree.

As discussed above, in view of the amendments to claims 1 and 15, Applicants suggest that the Poole reference fails to disclose each and every element of the rejected claims. Applicants additionally suggest that the Poole et al. reference similarly fails to disclose each and every element of the rejected claims, and also fails to supply the deficiency of Poole.

The system of Poole et al. is intended to be used for monitoring impurities in a liquid stream. The system therefore does not include a fluid supply. Instead, "the system continuously samples a process line or slipstream to obtain a liquid sample" (see col. 4, lines 10-11. The sample liquid is not delivered to an accumulator, rather it is input to a precision micropump 10, and then delivered to a droplet generator 14 at a constant flow rate (see col. 4, lines 24-30). This portion of the system of Poole et al. is depicted in a schematic taken from Fig. 1A, below:

Page 14 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3



Applicants therefore suggest that neither Poole nor Poole et al. disclose each and every element of the rejected claims, and that the cited references fail to establish the *prima facie* obviousness of the claims. In addition, Applicants suggest there is insufficient motivation to combine the Poole and Poole et al. references to arrive at the claimed invention.

The Poole et al. system is a monitoring system for determining impurities in pure liquids. When operated according to the description of Poole et al., the Poole et al. system discards 95% of the sampled liquid (see col. 5, lines 59-68). Applicants suggest that one of ordinary skill seeking to prepare a medicament dispenser would not consider a device that discarded 95% of the dispensed medicament before delivery. Furthermore, modifying the system of Poole et al. to deliver 100% of the sampled fluid would change the principle of the Poole et al. reference, and render the modified system unsatisfactory for its original purpose.

For at least the above reasons, Applicants suggest that the Examiner has failed to establish the *prima facie* obviousness of claims 6, 7 and 16-20, and they respectfully request the withdrawal of the rejection of the claims under 35 U.S.C. § 103.

Claims 1-5, 8-14 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. (US 6,234,167) in view of Poole.

The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a correction factor as used in the device of Cox et al. as taught by Poole in order to produce the desired performance characteristic in a given environment. Applicants respectfully disagree.

As discussed above, in view of the amendments to claims 1 and 28, Applicants suggest that the Poole reference fails to disclose each and every element of the rejected claims. Applicants further suggest that the Cox et al. reference also fails to disclose each and every element of the rejected claims. Furthermore, it is submitted that the Cox et al. reference fails to supply the deficiency of Poole.

The claims at issue recite a medicament dispenser or an inhaler that includes a medicament supply, an ejector in fluid communication with the medicament supply, an accumulator in fluid communication with the ejector, and a valve intermediate the medicament supply and the accumulator.

Cox et al. discloses an aerosol generator that includes a source of material 37, a tube 27, a heater 33 for heating the tube, and a valve 35 between the tube 27 and the source of material 37 (see col. 3, line 61 to col. 4, line 9). The device of Cox et al. is shown in Fig. 1, reproduced below.

Page 16 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3

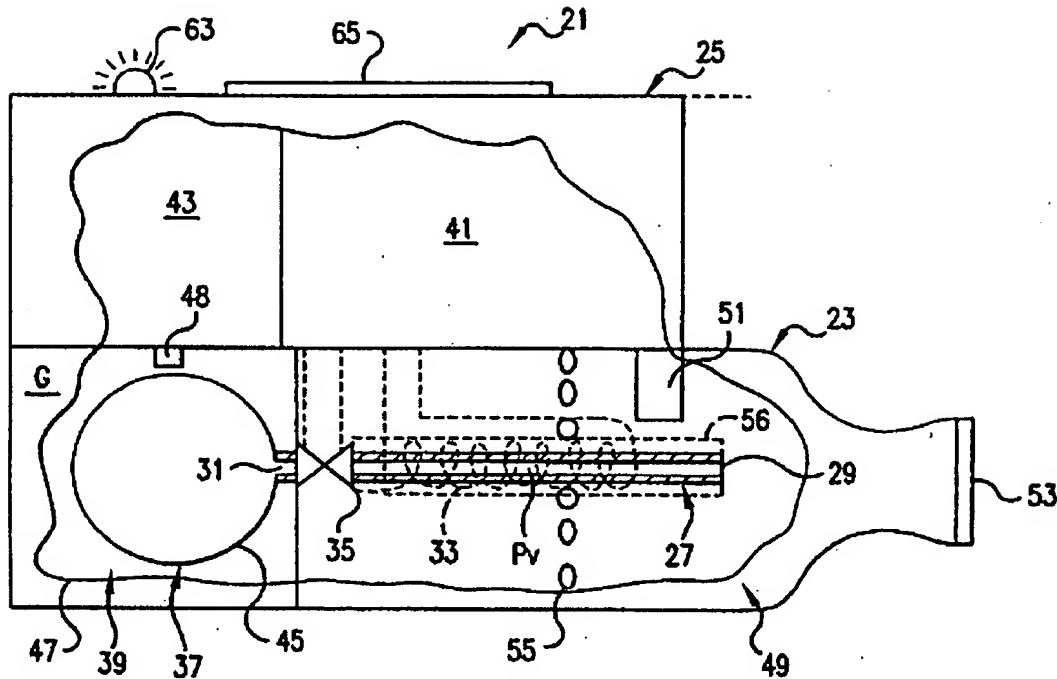


FIG.1

The material 37 is held within a flexible container 45 and pressurized by a gas supply G. When valve 35 is opened, the material is therefore forced into tube 27, where it can be volatilized by the heater 33.

The Cox et al. device fails to include an accumulator in fluid communication with the ejector, and fails to disclose a valve between the medicament supply and the accumulator. Applicants therefore respectfully suggest that even in combination, the Poole and Cox et al. references fail to disclose each and every element of the rejected claims, and therefore fail to establish the *prima facie* obviousness of the claims.

Furthermore, Applicants suggest that one of ordinary skill in the art would not be motivated to combine the teachings of the Poole and Cox et al. references, as the two references utilize very different strategies for aerosolizing a substance. Where Poole forces a liquid through orifices in a piezoelectric oscillator, Cox et al. simply forces the substance of interest into a tube and permits a heater to volatilize the substance so that it expands out of the tube. These dispensation strategies are incompatible, and are incapable of functioning in combination, and accordingly there can be no motivation or suggestion to combine the references as suggested by the Examiner.

Applicants suggest that the Examiner has failed to establish the *prima facie* obviousness of claims 1-5, 8-14 and 28, and therefore respectfully request the withdrawal of the rejection of the claims under 35 U.S.C. § 103.

Obviousness-type Double Patenting

Claims 1, 6-11, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application no. 10/375,794.

Claims 1-4, 14, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application no. 10/777,448.

Applicants acknowledge the obviousness-type double patenting rejections. Applicants urge the Examiner to reconsider these rejections in light of the revised claims. Terminal disclaimers were not filed to overcome the provisional nonstatutory double patenting rejections. However, Applicants would be willing to file a terminal

Page 18 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3

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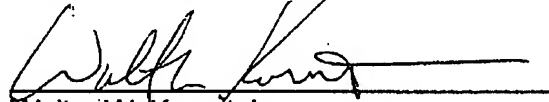
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disclaimer to further prosecution of the application to allowance if the Examiner concludes that the provisional nonstatutory double patenting rejections are proper and there are no other remaining issues.

Applicants believe that in view of the above amendments and remarks, this application is now in condition for allowance. Accordingly, Applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner K. Matter, Group Art Unit 3771, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on October 3, 2007.



Christie A. Doolittle

Page 19 - AMENDMENT
Serial No. 10/777,449
HP Docket No. 200309745-1
KH Docket No. HPCC 3B3